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15W

Joseph P. Balin



Attorney Docket No. CHM-013M1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of :
KENNETH D. R. SETCHELL et al. : Confirmation No.: 9470
Serial No.: 10/625,934 : Group Art Unit: 1614
Filed: 07/24/2003 :
COMPOSITIONS AND PRODUCTS CONTAINING S-EQUOL, AND METHODS
FOR THEIR MAKING

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
PURSUANT TO 37 CFR 1.56, 1.97 and 1.98

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR §§1.56, 1.97 and 1.98, Applicant request the Examiner to make of record the documents listed on the attached PTO/SB/08 form in connection with examination of the above-identified patent application. As provided in §1.97(g), no representation is made or intended that a thorough art search was made. As provided in 37 C.F.R. §1.97(h), this Information Disclosure Statement does not constitute an admission of any kind, and specifically is not an admission that the documents listed on attached form PTO/SB08 are, or are considered to be, material to the patentability of the above-identified patent application, as defined in 37 C.F.R. §1.56(b). In accordance with 37 C.F.R. §1.98(a)(2), Applicants are submitting copies of foreign patent documents and non-patent literature.

Applicants also respectfully request the Examiner to consider and make of record the co-pending applications listed on the attached page.

This information disclosure statement is being submitted under 37 C.F.R. §1.97(b)(3). Applicants have not received an Office Action on the merits in the present application. Therefore, no fee is believed to be due.

This submission does not represent that a search has been made or that no closer art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and Applicant determines that the cited documents do not constitute "prior art" under United States law, Applicant reserves the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

Respectfully submitted,

For: Kenneth D. R. SETCHELL et al.

By 

Daniel F. Nesbitt
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October 12/12, 2005

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				<i>Complete if Known</i>	
				Application Number	10/625,934
				Filing Date	07/24/2003
				First Named Inventor	Kenneth D. R. SETCHELL et al.
				Art Unit	1614
				Examiner Name	
Attorney Docket Number	CHM-013M1				

OCT 14 2005
 PATENT & TRADEMARK OFFICE

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U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
		US	4,390,559	06/28/1983	Zilliken	
		US	5,141,746	08/25/1992	Fleury et al.	
		US	5,352,384	10/04/1994	Shen	
		US	5,424,331	06/13/1995	Shlyankevich	
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		US	6,565,864 B2	05/20/2003	Pillai et al.	
		US	6,628,543	10/28/2003	Kang et al.	
		US	2002/0019377 A1	02/14/2002	Jenkins et al.	
		US	2002/0160064	10/31/2002	Zulli et al.	
		US	2003/0027772 A1	02/06/2003	Breton	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code ³	Number ⁴ -Kind Code ⁵ (if known)			
		Japan	H02-124883	05/14/1990	Kitasato Institute	Partial English Translation
		WO	93/23069	11/25/1993	Kelly, Graham, Edmund	
		WO	94/23716	10/27/1994	Tufts University School of Medicine	
		WO	96/10341	04/11/1996	Van Haaster, Joseph, Nicolas	
		WO	97/06273	02/20/1997	Fermalogic, Inc.	
		WO	98/48790	11/05/1998	Anticancer, Inc.	
		WO	02/087517	11/07/2002	Beiersdorf AG	Abstract
		WO	02/089757	11/14/2002	Beiersdorf AG	Abstract
		WO	04/022023	03/18/2004	Novogen Research	
		WO	04/026274	04/01/2004	Novogen Research PTY Ltd.	
		WO	04/039327 A2	05/13/2004	Colorado State University Research Foundation, Brigham Young University; Children's Hospital Medical Center	

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s) volume-issue number(s), publisher, city and/or country where published.	T ²
		LUND, TD et al., Equol is a Novel Anti-Androgen that Inhibits Prostate Growth and Hormone Feedback, Biol. Reprod., 2004 Apr; 70(4) 1188-95, E-Pub. 2003 Dec. 17	
		ATKINSON, C. et al, In Vitro Incubation of Human Feces with Daidzein and Antibiotics Suggests Interindividual Differences in the Bacteria Responsible for Equol Production, Amer. Society for Nutritional Sciences, 134:596-599, March 2004	
		SETCHELL, Kenneth, D.R.. et al. Phytoestrogens: The Biochemistry, Physiology, and Implications for Human Health of Soy Isoflavones, Am J. Clin Nutri 1998, Pgs. 1333S-1346S	

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				First Named Inventor	Kenneth D. R. SETCHELL et al.
				Art Unit	1614
				Examiner Name	
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		ALDERCREUTZ, H. et al, Determination of Urinary Lignans And Phytoestrogen Metabolites, Potential Antiestrogen and Anticarcinogens in Urine of Women on Various Habitual Diets, J. Steroid Biochem, Vol. 25, pp 791-797 (1996)	Abstract
		THOMPSON, M.A. et al., Characterization of the Estrogenic Properties of A Nonsteroidal Estrogen, Equol, Extracted from Urine of Pregnant Macaques Biol Reprod, Nov 1984; 31: 705 - 713.	
		HEDLUND, T.E. et al., Soy Isoflavonoid Equol Modulates the Growth of Benign and Malignant Prostatic Epithelial Cells in Vitro, The Prostate 54:68-78 (2003) accepted May 14, 2002	
		DUNCAN, A. M. et al., Premenopausal Equol Excretors Show Plasma Hormone Profiles Associated with Lowered Risk of Breast Cancer , Cancer Epidemiol, Biomarkers Prev Vol. 9: 581-586. June, 2000.	
		HWANG, J. et al., The Phytoestrogen Equol Increases Nitric Oxide Availability by Inhibiting Superoxide Production: An Antioxidant Mechanism for Cell-Mediated LDL Modification, Free Radical Biology & Medicine, Vol. 34, No. 10, pp. 1271-1282, (2003)	
		MUTHYALA, R. S., Equol, a Natural Estrogenic Metabolite from Soy Isofavones: Convenient Preparation and Resolution of R- and S- Equols and Their Differing Binding and Biological Activity Through Estrogen Receptors Alpha and Beta, Bioorganic & Medicinal Chemistry 12 pp 1559-1567 (2004), accepted November 19, 2003	
		SATHYAMOORTHY, N. et al., Differential Effects of Dietary Phyto-oestrogens Daidzein and Equol on Human Breast Cancer MCF-7 Cells, European Journal of Cancer, Volume 33, Issue 14, December 1997, Pages 2384-2389	Abstract
		OGAWARA, H., A specific Inhibitor for Tyrosine Protein Kinase from Pseudomonas, The Journal of Antibiotics, Vol. 39(4), Apr. 1936, 606-608	

Examiner Signature		Date Considered	
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COPENDING U.S. PATENT APPLICATIONS				
Examiner Initials*	Applicant(s)	Serial No.	Filing Date	Atty. Docket No.
	Setchell, et al.	10/625,989	07/24/2003	CHM-013M2
	Lephart, et al	10/533,045	04/28/2005	CSU-001M
	Lephart, et al	11/059,951	02/17/2005	CSU-002M